

AUG 30 2007

**Section 5 – 510(k) Summary**

<b>Submitter:</b>	Cardiovascular Systems, Inc 651 Campus Drive, St. Paul, MN 55112
<b>Contact Person:</b>	Cindy Setum, Ph.D., Vice President, Clinical Affairs phone: 651-259-1650, fax: 651-259-1697
<b>Date Prepared:</b>	May 22, 2007
<b>Trade Name:</b>	Diamondback 360°™ Orbital Atherectomy System for Treatment of A-V Shunt Stenosis
<b>Classification:</b>	Class II Peripheral Atherectomy Catheter 21 CFR §870.4875
<b>Product Code:</b>	MCW
<b>Predicate Device(s):</b>	The subject device is equivalent to the following device: K041630, Orbital Atherectomy System for Treatment of A-V Shunt Stenosis
<b>Device Description:</b>	The Diamondback 360°™ Orbital Atherectomy System (OAS) is intended for use in treatment of artificial arteriovenous dialysis fistula stenosis. An artificial arteriovenous dialysis fistula (A-V shunt) is placed sub-dermal to support kidney dialysis. A consequence of the body's reaction to the foreign material of the A-V shunt is to form clots and neointimal stenosis of the A-V Shunt. The most common location for the A-V shunt stenosis is at the shunt to vein anastomosis. It is this region that the Cardiovascular Systems, Inc. Orbital Atherectomy System (CSI OAS) is applied to remove neointimal tissue causing a stenosis in the A-V shunt.
<b>Intended Use:</b>	The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).
<b>Functional and Safety Testing:</b>	To verify that device design met its functional and performance requirements, representative sample of the device underwent mechanical testing and biocompatibility in accordance with ISO 10993.
<b>Conclusion:</b>	Cardiovascular Systems, Inc. considers the Diamondback 360°™ Orbital Atherectomy System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 30 2007

Cardiovascular Systems, Inc.  
c/o Michael J. Kallok, Ph.D.  
Chief Scientific Officer  
651 Campus Drive  
St. Paul, MN 55112-3495

Re: K071427  
Diamondback 360™ Orbital Atherectomy System  
Regulation Number: 21 CFR 870.4875  
Regulation Name: Intraluminal artery stripper  
Regulatory Class: Class II (Two)  
Product Code: MCW  
Dated: August 3, 2007  
Received: August 6, 2007

Dear Dr. Kallok:

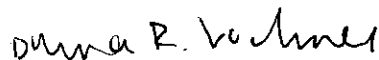
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### Section 4 – Indications For Use Statement

510(k) Number (if known): K071427

Device Name: Diamondback 360°™ Orbital Atherectomy System for Treatment of A-V Shunt Stenosis

##### Indications for Use:

The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K071427